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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Mary Lynne Hedley et al. Art Unit : 1633
Serial No. : 10/758,970 Examiner : Ileana Popa
Filed : January 16, 2004 Conf. No. : 6224
Title : CONTINUOUS-FLOW METHOD FOR PREPARING MICROPARTICLES

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

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Applicant : Mary Lynne Hedley et al.
Serial No. : 10/758,970
Filed : January 16, 2004
Page : 2 of 2

Attorney's Docket No.: 08191-012002

This statement is being filed before the receipt of a first Office Action on the merits.
Please apply any charges or credits to Deposit Account No. 06-1050 referencing Attorney
Docket No. 08191-012002.

Respectfully submitted,

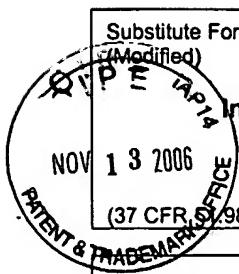
Date: November 10, 2006



Jack Brennan
Reg. No. 47,443

Fish & Richardson P.C.
Citigroup Center
52nd Floor
153 East 53rd Street
New York, New York 10022-4611
Telephone: (212) 765-5070
Facsimile: (212) 258-2291

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Substitute Form PTO-1449

(Modified)

U.S. Department of Commerce
Patent and Trademark OfficeAttorney's Docket No.
08191-012002Application No.
10/758,970
**Information Disclosure Statement
by Applicant**
 (Use several sheets if necessary)

(37 CFR, § 1.98(b))

Applicant
Mary Lynne Hedley et al.Filing Date
January 16, 2004Group Art Unit
1633**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3,520,970	07/21/1970	Lehmann et al.			
	AB	3,737,337	06/05/1973	Schnoring et al.			
	AC	3,775,537	11/27/1973	Lehmann et al.			
	AD	3,821,422	06/28/1974	Morse et al.			
	AE	3,835,221	09/10/1974	Fulberth et al.			
	AF	3,860,733	01/14/1975	Morse et al.			
	AG	3,943,063	03/09/0976	Morishita et al.			
	AH	3,954,959	05/04/1976	Pedersen et al.			
	AI	3,972,999	08/03/1976	Tsuk			
	AJ	4,016,254	04/05/1977	Seager			
	AK	4,083,949	04/11/1978	Benedikt			
	AL	4,182,778	01/08/1980	Hall et al.			
	AM	4,293,539	10/06/1981	Ludwig et al.			
	AN	4,321,253	03/23/1982	Beatty			
	AO	4,384,975	05/24/1983	Fong			
	AP	4,462,839	0/31/1984	McGinley et al.			
	AQ	4,518,433	05/21/1985	McGinley et al.			
	AR	4,623,588	11/18/1986	Nuwayser et al.			
	AS	4,637,905	01/20/1987	Gardner			
	AT	4,741,872	05/03/1988	DeLuca et al.			
	AU	4,818,542	04/04/1989	DeLuca et al.			
	AV	4,897,268	01/30/1990	Tice et al.			
	AW	5,075,109	12/24/1991	Tice et al.			
	AX	5,084,553	01/28/1992	Hess et al.			
	AY	5,100,669	03/31/1992	Hyon et al.			
	AZ	5,126,147	06/30/1992	Silvestri et al.			
	AAA	5,160,745	11/03/1992	DeLuca et al.			

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 08191-012002	Application No. 10/758,970
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Mary Lynne Hedley et al.	
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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	ABB	5,180,765	01/19/1993	Sinclair			
	ACC	5,279,708	01/18/1994	Wood et al.			
	ADD	5,354,556	10/11/1994	Sparks et al.			
	AEE	5,366,733	11/22/1994	Brizzolara et al.			
	AFF	5,407,609	04/18/1995	Tice et al.			
	AGG	5,413,797	05/09/1995	Khan et al.			
	AHH	5,417,986	05/23/1995	Reid et al.			
	AII	5,531,925	07/02/1996	Landh et al.			
	AJJ	5,580,859	12/03/1996	Felgner et al.			
	AKK	5,589,466	12/31/1996	Felgner et al.			
	ALL	5,622,649	04/22/1997	Hunter et al.			
	AMM	5,622,657	04/22/1997	Takada et al.			
	ANN	5,639,473	06/17/1997	Grinstaff et al.			
	AOO	5,648,096	07/15/1997	Gander et al.			
	APP	5,650,173	07/22/1997	Ramstack et al.			
	AQQ	5,651,990	07/29/1997	Takada et al.			
	ARR	5,652,283	07/29/1997	Boeckh et al.			
	ASS	5,656,297	08/12/1997	Bernstein et al.			
	ATT	5,656,469	08/12/1997	Tresco et al.			
	AUU	5,662,938	09/02/1997	Vert et al.			
	AVV	5,690,954	11/25/1997	Illum			
	AWW	5,700,486	12/23/1997	Canal et al.			
	AXX	5,723,269	03/03/1998	Akagi et al.			
	AYY	5,792,366	08/11/1998	Coville			
	AZZ	5,811,128	09/22/1998	Tice et al.			
	AAAA	5,814,344	09/29/1998	Tice et al.			
	ABBB	5,820,883	10/13/1998	Tice et al.			

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	ACCC	5,853,763	12/29/1998	Tice et al.			
	ADDD	5,919,408	07/06/1999	Muller et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Abst	
							Yes	No
	AEEE	027 662	04/29/1981	EP				
	AFFF	122 036	10/17/1984	EP				
	AGGG	127 713	11/02/1989	EP				
	AHHH	145 240	06/19/1985	EP				
	AIII	161 640	11/21/1985	EP				
	AJJJ	179 023	04/23/1986	EP				
	AKKK	2 185 979	08/05/1987	GB				
	ALLL	2 126 685	10/18/1993	CA				
	AMMM	2 147 501	05/15/1985	GB				
	ANNN	248 531	12/09/1987	EP				
	AOOO	250 038	12/23/1987	EP				
	APPP	258 749	03/09/1988	EP				
	AQQQ	266 119	05/04/1988	EP				
	ARRR	302 582	12/17/1997	EP				
	ASSS	330 180	01/13/1993	EP				
	ATTI	333 523	07/17/1996	EP				
	AUUU	334 062	09/27/1989	EP				
	AVVV	374 531	06/27/1990	EP				
	AWWW	451 390	10/16/1991	EP				
	AXXX	451 391	10/16/1991	EP				
	AYYY	467 389	01/22/1992	EP				
	AZZZ	471 036	02/19/1992	EP				

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							Yes	No
	AAAAAA	475 178	03/18/1992	EP				
	ABBBB	531 497	08/13/1997	EP				
	ACCC	635 261	01/25/1995	EP				
	ADDD	706 792	04/17/1996	EP				
	AEEE	737 750	10/16/1996	EP				
	AFFF	WO 94/04171	03/03/1994	WIPO				
	AGGG	WO 94/04260	03/03/1994	WIPO				
	AHHH	WO 94/09898	05/11/1994	WIPO			X	
	AIIII	WO 94/23699	10/27/1994	WIPO				
	AJJJJ	WO 94/23738	10/27/1994	WIPO				
	AKKK	WO 94/28873	12/22/1994	WIPO				
	ALLL	WO 94/28874	12/22/1994	WIPO				
	AMMM	WO 95/05853	03/02/1995	WIPO				
	ANNN	WO 95/07072	03/16/1995	WIPO			X	
	AOOO	WO 95/17167	06/29/1995	WIPO			X	
	APPP	WO 95/20660	08/03/1995	WIPO				
	AQQQ	WO 95/21250	08/10/1995	WIPO				
	ARRR	WO 95/24929	09/21/1995	WIPO				
	ASSS	WO 95/31184	11/23/1995	WIPO				
	ATTT	WO 95/31187	11/23/1995	WIPO				
	AUUU	WO 95/35097	12/28/1995	WIPO				
	AVVVV	WO 96/00295	01/04/1996	WIPO				
	AWWWWW	WO 96/11671	04/25/1996	WIPO				
	AXXXXX	WO 96/29998	10/03/1996	WIPO				
	AYYYYY	WO 96/36317	11/21/1996	WIPO				
	AZZZZZ	WO 97/36578	10/09/1997	WIPO				
	AAAAAA	WO 97/42940	11/20/1997	WIPO				

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Foreign Patent Documents or Published Foreign Patent Applications							
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							Yes
	ABBBBB	WO 98/35654	08/20/1998	WIPO			

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	ACCCCC	Alexakis, T. et al., "Microencapsulation of DNA With Alginete Microspheres and Crosslinked Chitosan Membranes for in Vivo Application," <i>Appl. Biochem. Biotech.</i> 50:93-106, 1995.
	ADDDDD	Alpar et al., "Potential of Particulate Carriers for the Mucosal Delivery of DNA Vaccines," <i>Biochemical Society Transactions</i> , 25:337S, 1997.
	AEEEEEE	Amagai et al., "Autoantibodies against a Novel Epithelial Cadherin in Pemphigus Vulgaris, a Disease of Cell Adhesion," <i>Cell</i> , 67:869-877, 1991.
	AFFFFF	Bodmeier et al., "The Preparation and Evaluation of Drug-Containing Poly(dl-lactide) Microspheres Formed by the Solvent Evaporation Method," <i>Pharmaceutical Research</i> , 4:465, 466, 571, 1987.
	AGGGGG	Chen et al., "Protective Immunity Induced by Oral Immunization with a Rotavirus DNA Vaccine Encapsulated in Microparticles." <i>Journal of Virology</i> 72(7):5757-5761, 1998.
	AHHHHH	Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success." <i>Science</i> 270:404-410, 1995.
	AIIIII	Eldridge et al., "Biodegradable and Biocompatible...Toxin-Neutralizing Antibodies." <i>Infection and Immunity</i> 59(9):2978-2986, 1991.
	AJJJJJ	Eldridge et al., "Controlled Vaccine...Microspheres Target The Peyer's Patches." <i>Journal of Controlled Release</i> 11(1-3):205-214, 1990.
	AKKKKK	Eppstein et al., "Alternative Delivery Systems for Peptides and Proteins As Drugs." <i>CRC Critical Review in Therapeutic Drug Carrier Systems</i> 5:99-139, 1988.
	ALLLLL	Etlinger, "Carrier Sequence Selection-one key to successful vaccines," <i>Immunology Today</i> 13(2):52-55, 1992.
	AMMMMM	Florence, "The Oral Absorption of Micro- and Nanoparticulates: Neither Exceptional Nor Usual." <i>Pharm. Res.</i> 14(3):259-266, 1997.
	ANNNNN	Gref et al., "Biodegradable Long-Circulating Polymeric Nanospheres," <i>Science</i> , 263:1600-1603, 1994.
	AOOOOC	Gunzburg and Salmons, "Virus vector design in gene therapy." <i>Molecular Medicine Today</i> 410-417, 1995.
	APPPPP	Heard, "HLA and autoimmune disease," <i>HLA and Disease</i> , pp. 123-151, 1994.
	AQQQQQ	Hedley, "Genetic Modulation of Antigen Presentation," <i>MHC Molecules: Expression, Assembly & Function</i> , Ch. 17, pp. 281-294; Eds., Robert G. Urban and Roman M. Chicz; R.G. Landes & Co., 1976.
	ARRRRR	Jacobs et al., "High-Level Expression of the Tick-Borne Encephalitis Virus NS1 Protein by Using an Adenovirus-Based Vector: Protection Elicited in a Murine Model." <i>J. Virol.</i> , 66(4):2086-2095, 1992.
	ASSSSS	Jacobs et al., "Protection elicited by a replication-defective adenovirus vector expressing the tick-borne encephalitis virus non-structural glycoprotein NS1." <i>J. Gen. Virol.</i> 75: 2399-2402, 1994.
	ATTTTT	Jepson et al., "Comparison of Poly(DL-Lactide-co-Glycolide) and Polystyrene Microsphere Targeting to Intestinal M Cells." <i>J. Drug Targeting</i> , 1:245-249, 1993.

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	AUUUUU	Jeyanthi et al., "Development of a Biodegradable...Peptide," Pharm. Res., Vol. 8, No. 10, October 1991, PDDD 7097.
	AVVVVV	Jones et al. "Oral Delivery of Micro-Encapsulated DNA Vaccines," Dev. Biol. Stand. Bassel, Karger, 92:149-155, 1998.
	WWWW	Jones et al., "Orally Administered Microencapsulated Bordetella pertussis Fimbriae Protect mice from B. pertussis Respiratory Infection," Infect. And Immun., 64(2):489-494, 1996.
	AXXXXX	Jones et al., "Poly (DL - lactide-co-glycolide)-Encapsulated plasmid DNA Elicits Systemic and Mucosal Antibody Responses to Encoded Protein After Oral Administration," Vaccine, 15:814-817, 1997.
	AYYYYY	Jones et al., "Poly(lactide-co-glycolide) microencapsulation vaccine antigens," J. Biotech., 44:29-36, 1996.
	AZZZZZ	Jones et al., "Protection of mice from Bordetella pertussis respiratory infection using microencapsulated pertussis fimbriae." Vaccine, 13(7): 675-681, 1995.
	AAAAAA	Kreuter, "Nanoparticles and microparticles for drug and vaccine delivery." J. Anat., 189:503-505, 1996.
	ABBBBB	Ledley, "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products." Human Gene Therapy 6(9):1129-1144, 1995.
	ACCCCC	Lewis et al., "Biodegradable poly(L-lactic acid) matrices for the sustained delivery of antisense oligonucleotides," J. Controlled Release, 37:173-183, 1995.
	ADDDDD	Lewis, "Controlled Release of Bioactive Agents From Lactide/Glycolide Polymers," Biodegradable Polymers as Drug Delivery Systems, Ch. 1, pp. 1-41; Eds. Mark Chasin and Robert Langer; Marcel Dekker, Inc.
	AEEEEEE	Miller et al., "Comet Assay Reveals DNA Strand Breaks Induced by Ultrasonic Cavitation In Vitro." Ultrasound in Med. & Biol. 21(6):841-848, 1995.
	AFFFFF	Morris et al., "Potential of Polymer Microencapsulation technology for vaccine innovation." Vaccine 12(1):5-11, 1994.
	AGGGGG	Murphy et al., "A novel MHC class II epitope expressed in thymic medulla but not cortex," Nature, 338:765-768, 1989.
	AHHHHH	Nakano et al., "Sustained Urinary Excretion of Sulfamethizole Following Oral Administration of Enteric Coated Microcapsules in Humans," International Journal of Pharmaceutics, 4:291-298, 1980.
	AIIIII	Nellore et al., "Application of biodegradable...Hepatitis B Surface Antigen Vaccination System." Pharmaceutical Research 8(10):S151, Abst. No. PDD 7098 , 1991.
	AJJJJJ	Neutra et al., "Epithelial M Cells: Gateways for Mucosal Infection and Immunization." Cells 86:345-348, 1996.
	AKKKKK	O'Hagan, "The intestinal uptake of particles and the implications for drug and antigen delivery," J. Anat., 189:477-482, 1996.
	ALLLLL	Puyal et al., "A new cationic liposome encapsulating genetic material a potential delivery system for polynucleotides," 228(3):697-703, 1995.
	MMMMMM	Rajasubramanian et al., "Fabrication of Resorbable Microporous Intravascular Stents for Gene Therapy Applications." ASAIO Journal 40(3):584-589, 1994.
	ANNNNN	Sah et al., "Biodegradable microcapsules prepared by...on their morphology and protein release." Journal of Microencapsulation 12(1):59-69, 1995.

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	AOOOOO	Shimoda et al., "HLA DRB4 0101-restricted Immunodominant T Cell Autoepitope of Pyruvate Dehydrogenase Complex in Primary Biliary Cirrhosis: Evidence of Molecular Mimicry in Human Autoimmune Diseases," <i>J. Exp. Med.</i> , 181:1835-1845, 1995.
	APPPPPP	Steinman, "Escape from 'Horror Autotoxicus': Pathogenesis and Treatment of Autoimmune Disease," <i>Cell</i> , 80:7-10, 1995.
	AQQQQQ	Tomlinson et al., "Controllable gene therapy Pharmaceutics of non-viral gene delivery systems," <i>Journal of Controlled Release</i> , 39:357-372, 1996.
	ARRRRRI	Truong, V.L. et al., "Immuno-microsphere as Gene Delivery Vehicle: Targeting of LAMP-1 to Lysosomal Membrane," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> 21:142-143, 1994.
	ASSSSSS	Truong-Le, V.L. et al., "Gene Transfer by Gelatin-DNA Coacervate," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> 22:466-467, 1995.
	ATTTTTT	Urban et al., "The Discovery and Use of HLA-Associated Epitopes as Drugs," <i>Critical Reviews in Immunology</i> , 17:387-397, 1997.
	AUUUUUU	Visscher et al., "Biodegradation of and tissue...microcapsules." <i>J. Biomed. Mater. Res.</i> 19(3):349-365, 1985.
	AVVVVVV	Whalen, "DNA Vaccines for Emerging Infectious Diseases: What If?" <i>Emerging Infectious Diseases</i> 2(3):168-175, 1996.

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